

Docket No. 2003-003R1 Application Serial No. 10/790,956
Inventor: Carlson et al.
Title: Evaluating Effects Of Exposure Conditions On Drug Samples

Over Time

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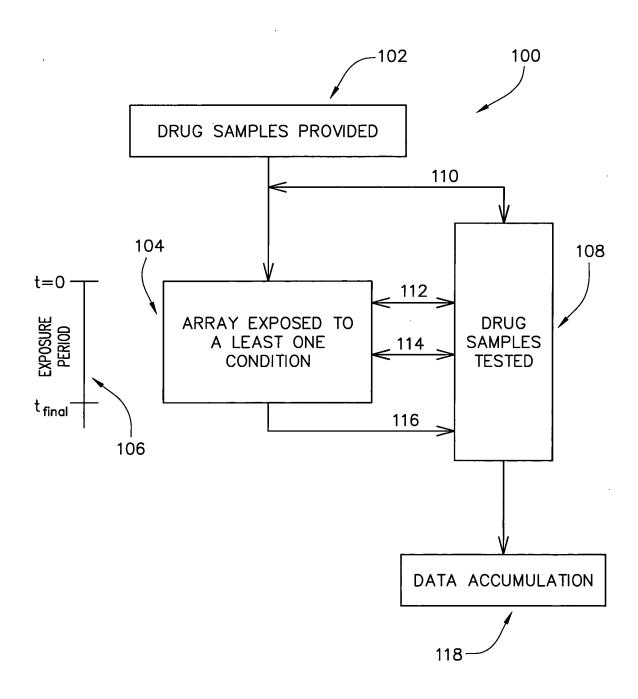
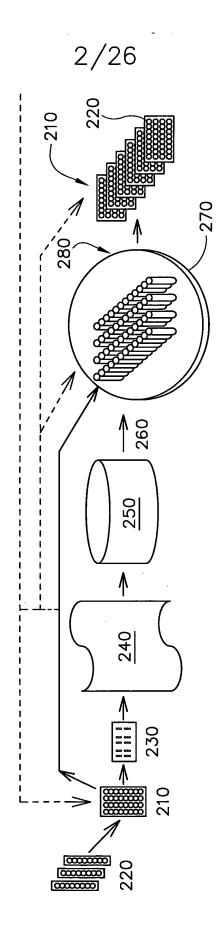


FIGURE 1

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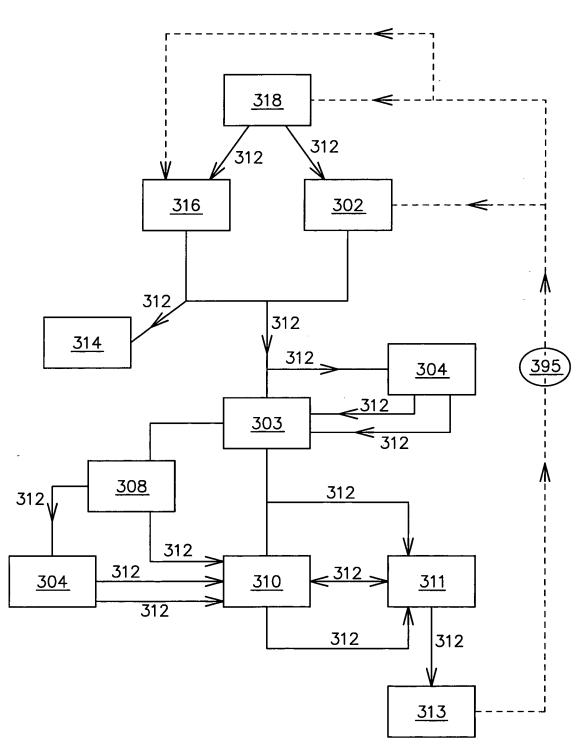


FIGURE 3

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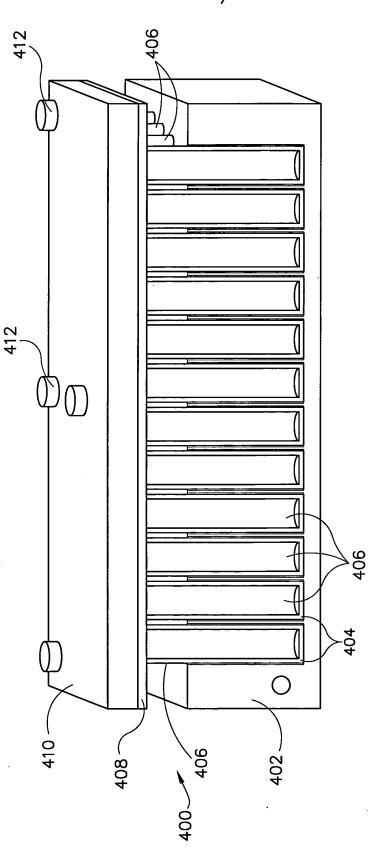
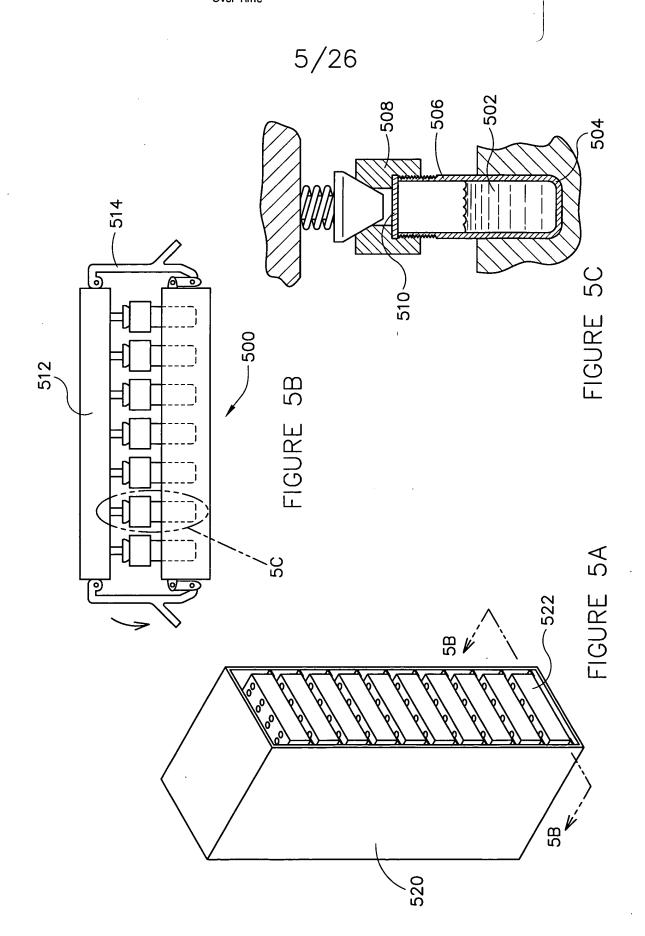


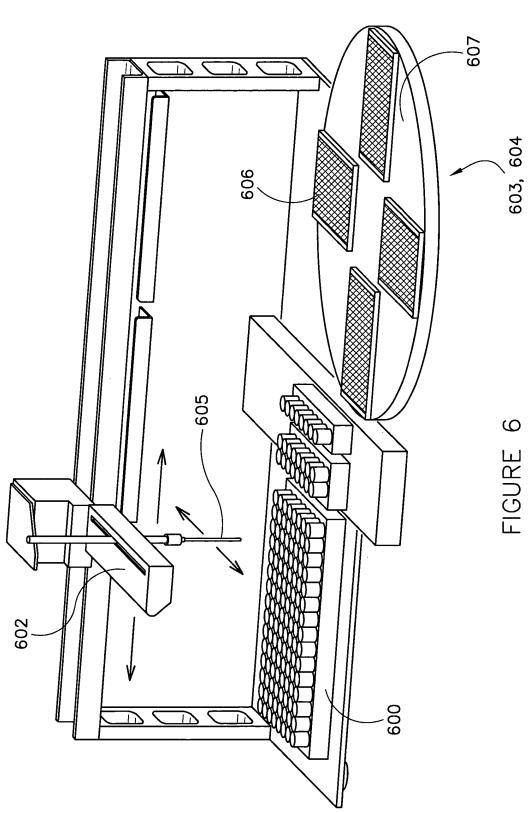
FIGURE 4

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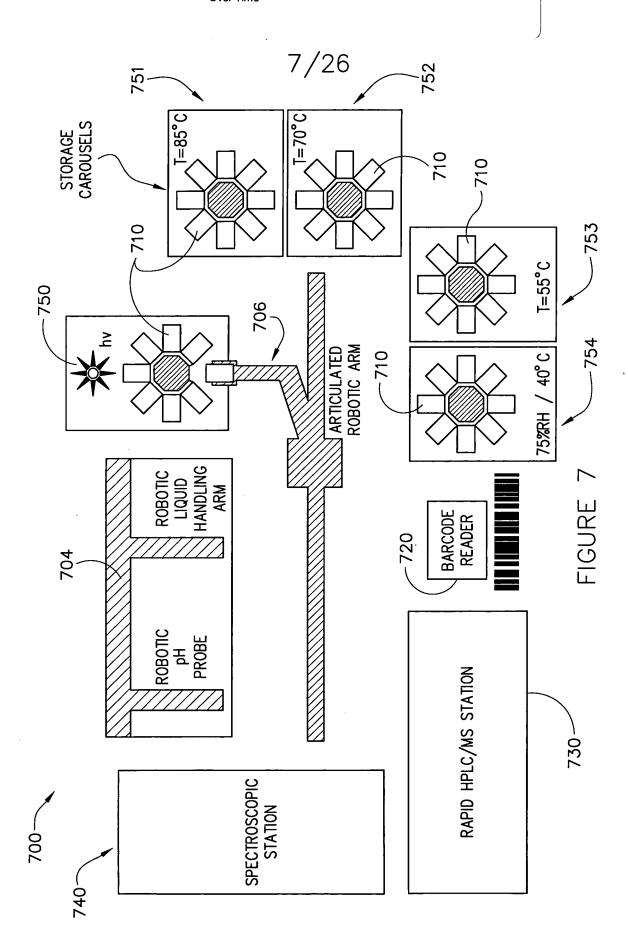


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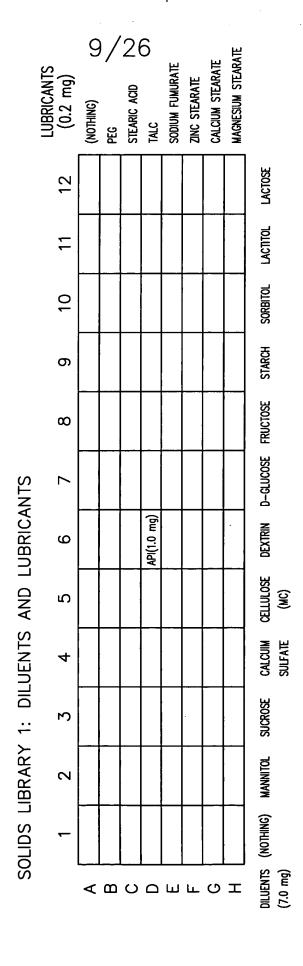
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		8/26				10.0 mg/mL			
		0.4 mg/mL	2.0 mg/mL	10.0 mg/mL	50.0 mg/mL	ETHANOL (20wt%)	PROPYLENE GLYCOL (20wt%)	AIBN (1eq)	H00H (1eq)
12	12								
11	11								
10 11 12	9   10   11   12								
6	6 1								
8	8		·						
7	рн 7								
9	9	ļ							
5	5				-				
4	4								
3	3								
2	2		·						
<del></del>	UNCONTROLLED	A	В	C		E	L	G	

AQUEOUS SOLUTIONS WITH A TOTAL VOLUME OF 800 uL/well

EXCIPIENT COMPATIBILITY - SOLIDS FORMULATIONS

Title: Evaluating Effects Of Exposure Conditions On Drug Samples Over Time



8B FIGURE

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> DESSICANT COLORANT

> > CALCIUM SILICATE

TALC

MAGNESIUM Oxide

CITRIC ACID POVIDONE

(NOTHING)

CITRIC ACID OXIDE

(NOTHING)

MAGNESIUM OXIDE

CITRIC ACID

(NOTHING)

MAGNESIUM Oxide

CITRIC ACID (NOTHING)

(NOTHING)

펍

BINDER

HYDROXYPROPYL METHYLCELLULOSE

CARBOXYMETHYLCELLULOSE, SODIUM

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(NOTHING) IKON OXIDE CALCIUM SILICATE SILICON DIOXIDE SILICON DIOXIDE GLIDANT (NOTHING) (NOTHING) TALC SOLIDS LIBRARY 2: FIXED DILUENT AND LUBRICANT WITH BINDERS, GLIDANTS, COLORANTS, ACIDIFIERS, ALKYLIZERSS 12 5 တ  $\infty$ 10 mg DESSICANT 1.0 mg COLORANT 1.0 mg GLIDANT / Θ S 1 eq Ph ADJUSTER 5.0 mg BINDER 4 3 7.0 mg FIXED DILUENT 2.0 mg FIXED DILUENT 2 1.0 mgdc **КВООШГОІ** 

EXCIPIENT COMPATIBILITY - SOLIDS FORMULATIONS

FIGURE 8C

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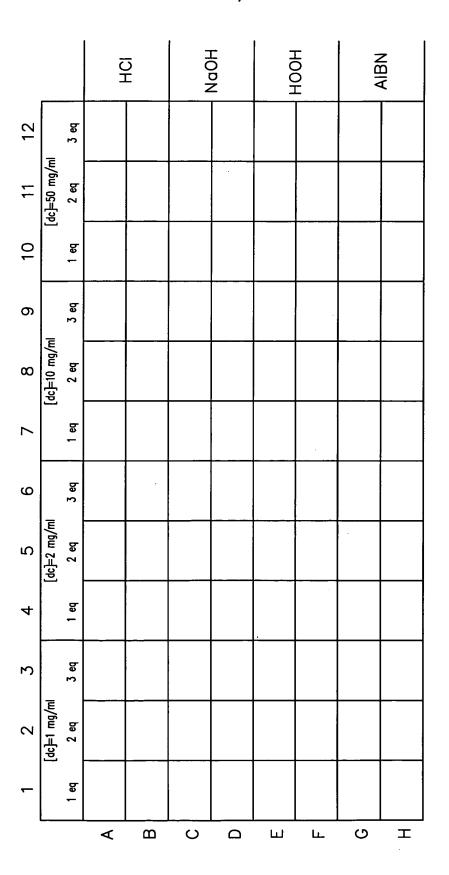


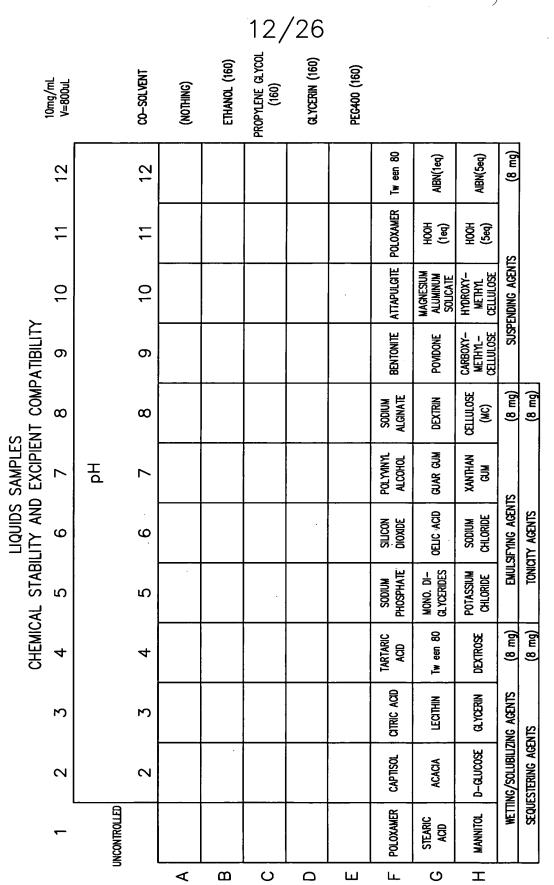
FIGURE 8D

TOTAL VOLUME = 800uL/well dc = DRUG CANDIDATE

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8 E FIGURE

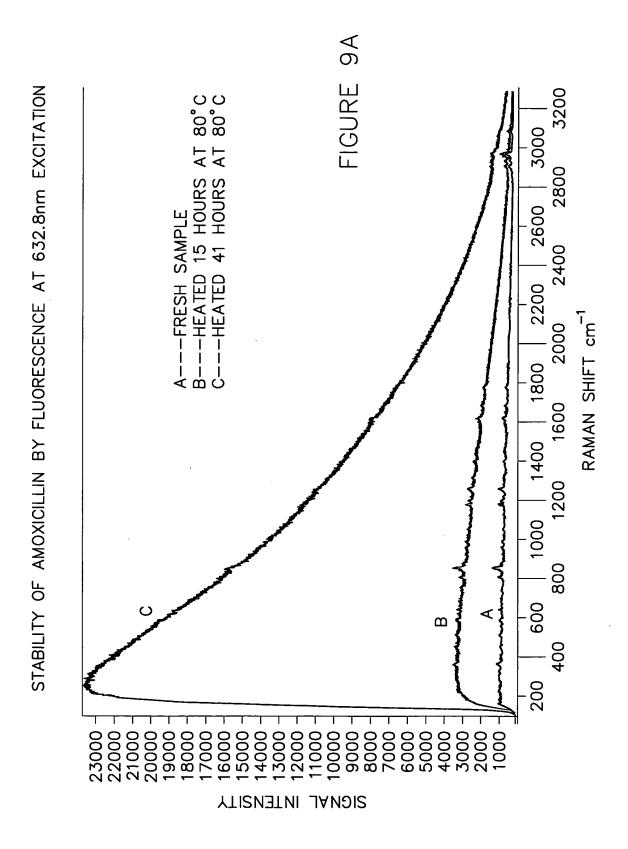
Docket No. 2003-003R1 Inventor: Carlson et al.

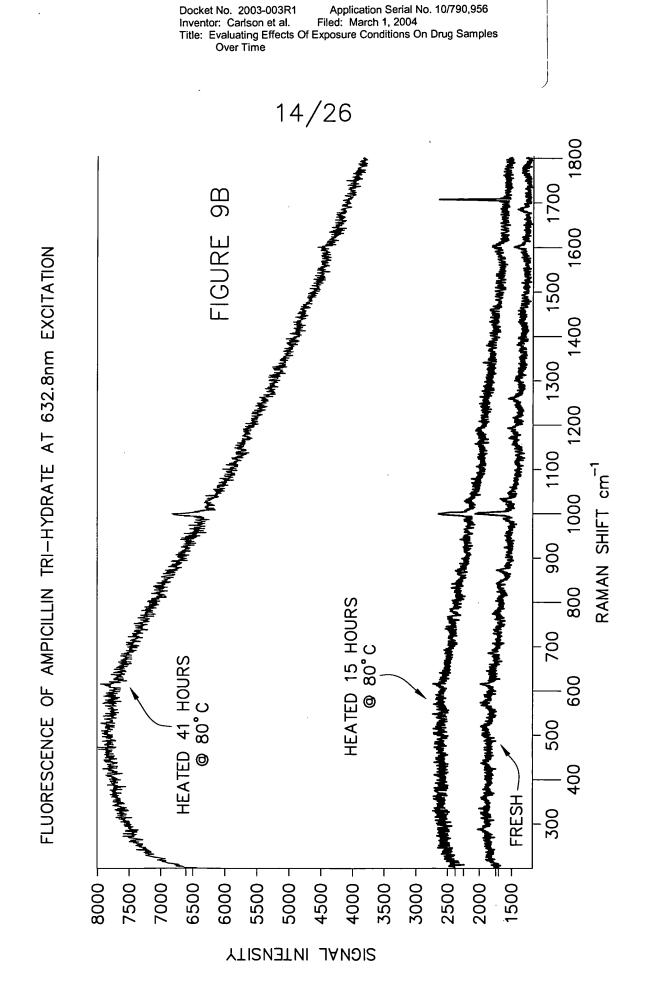
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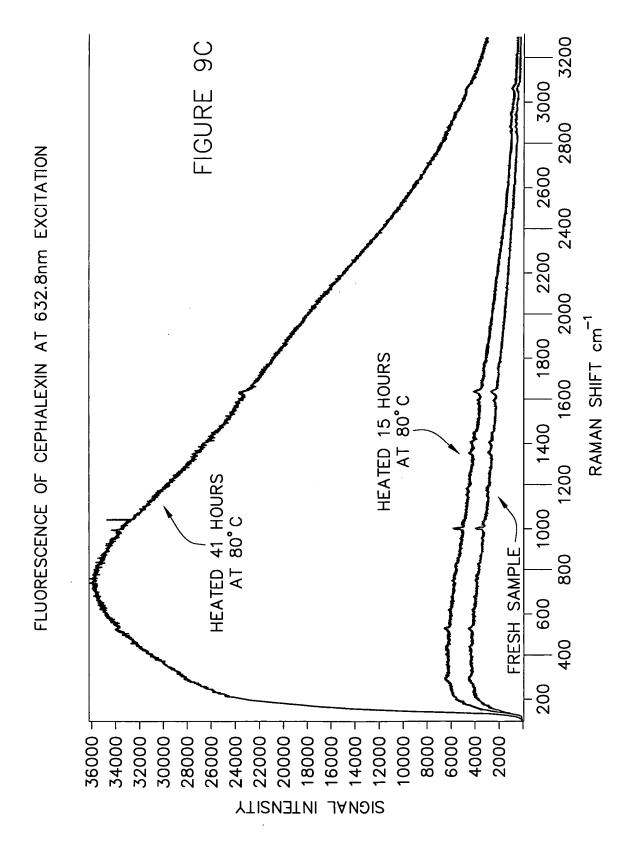




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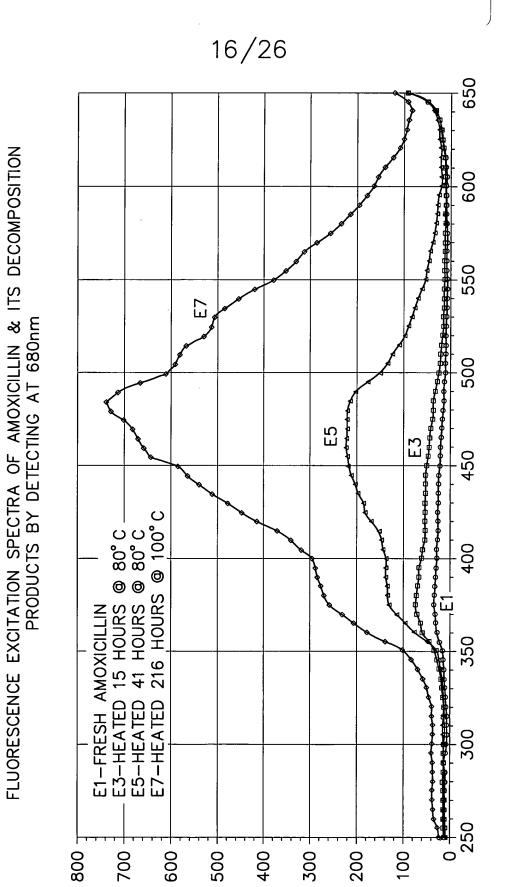


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FIGURE 9D



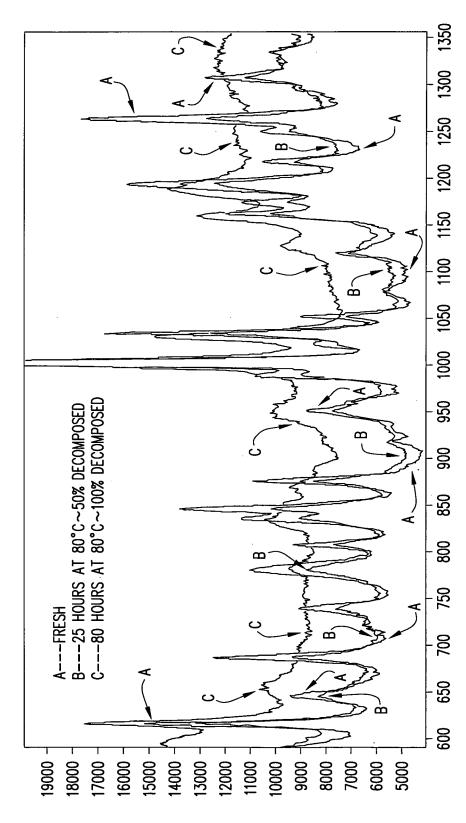
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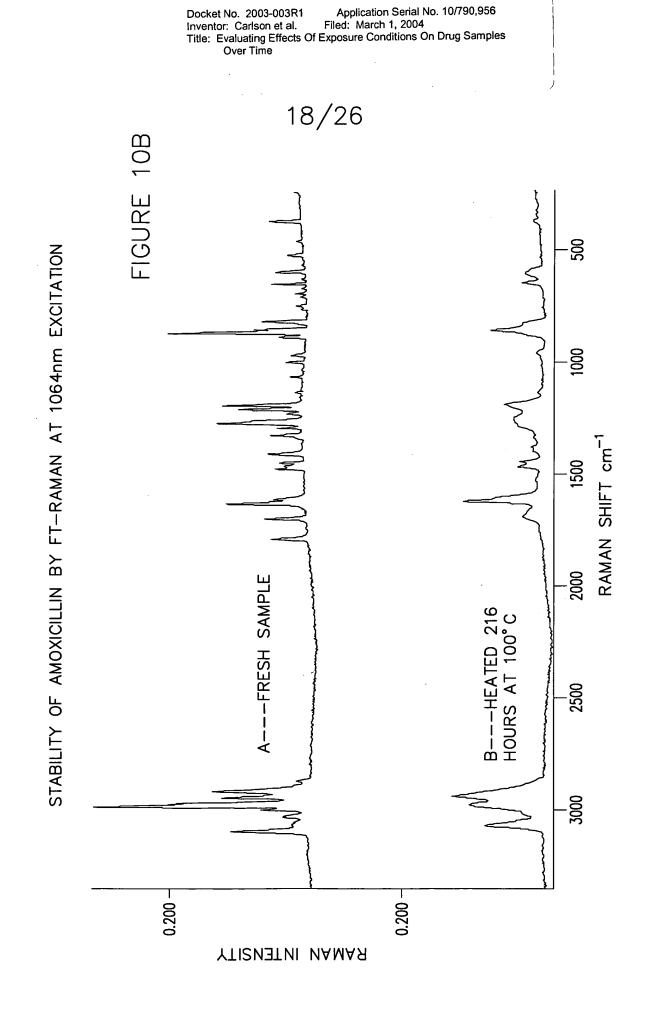
Ex WAVELENGTH IN nm (Em: 680nm)

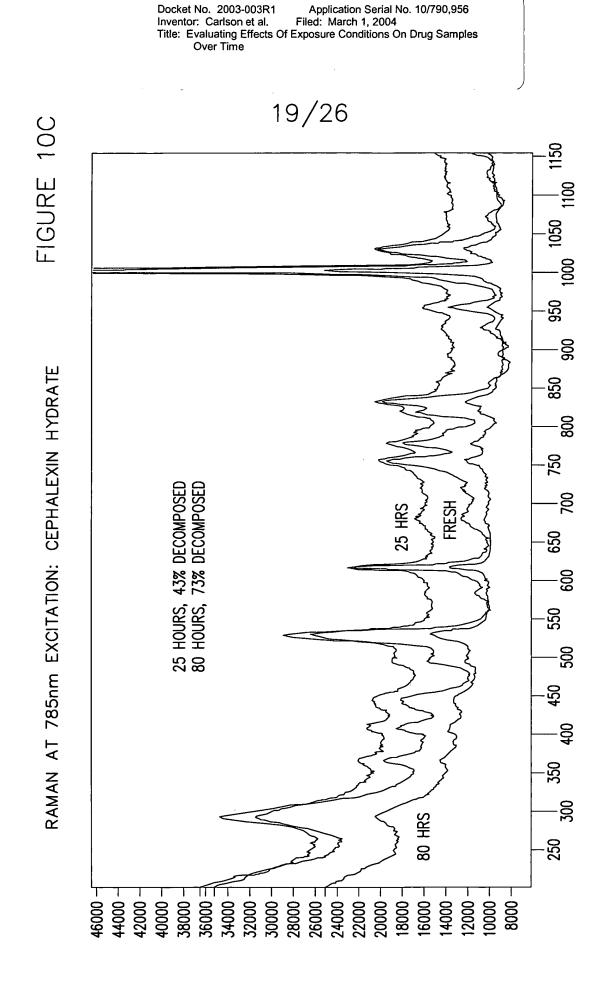
FIGURE 10A

RAMAN AT 785nm EXCITATION: AMPICILLIN TRIHYDRATE

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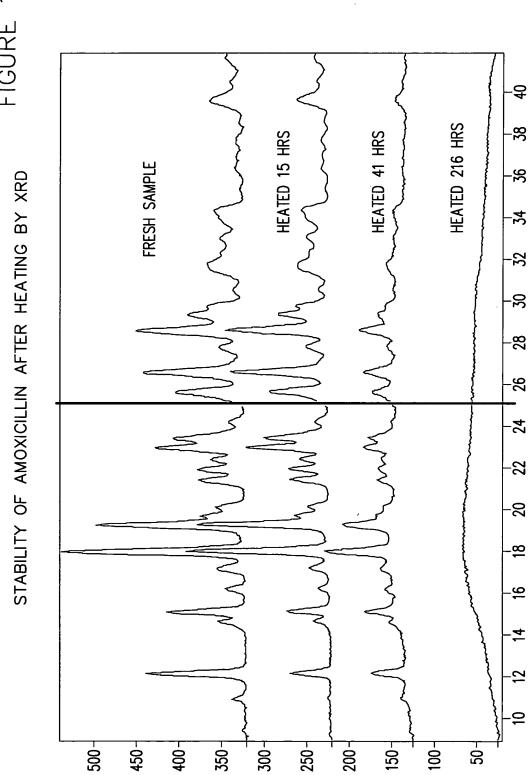
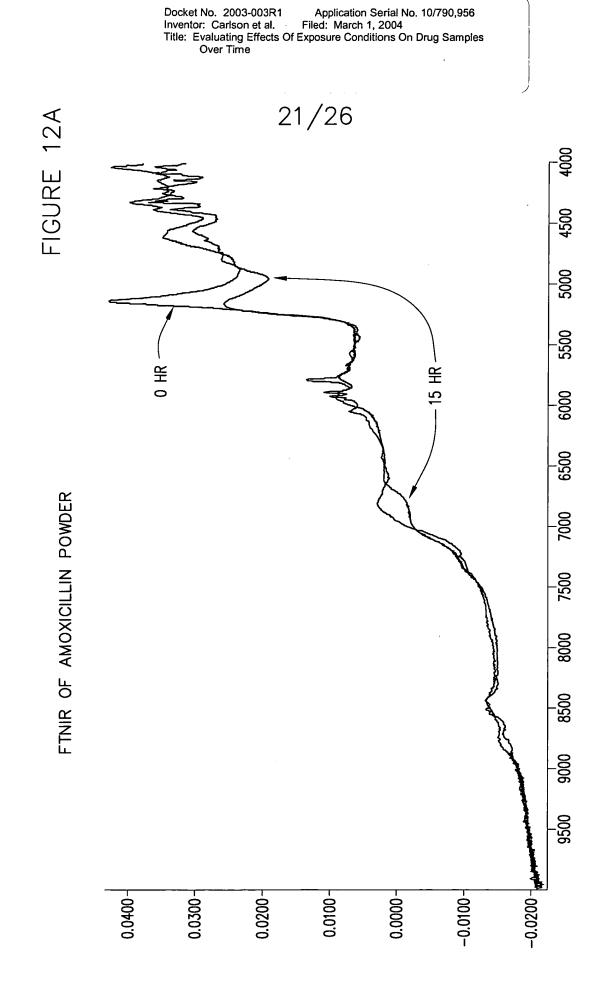


FIGURE 11



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Over Time 22/26 FIGURE 12B FTNIR OF CEPHALEXIN POWDER IN 8-mL VIALS AFTER 0, 25, 80 HRS @ 80°C 5000 5200 0 HR ----25 HR ---80 HR 0009

5.00-

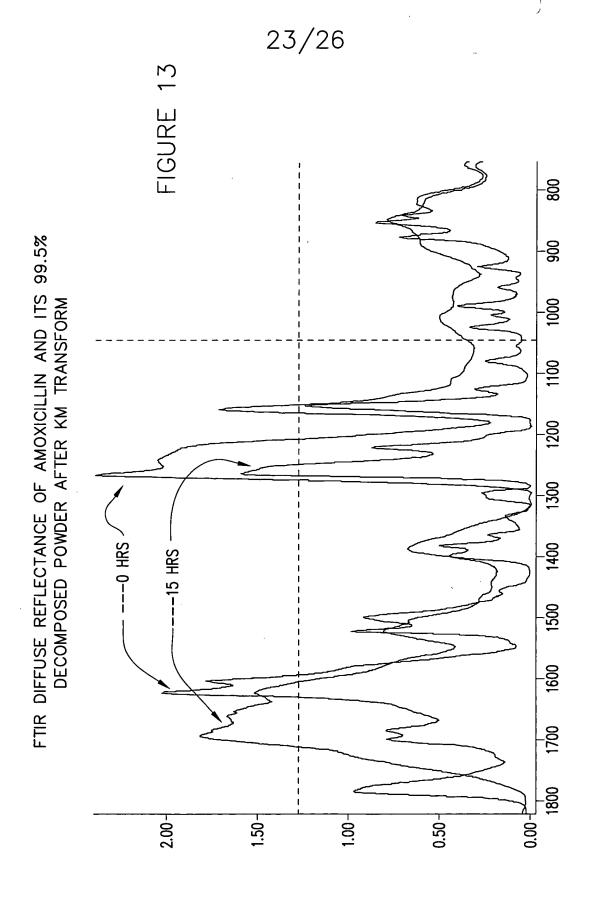
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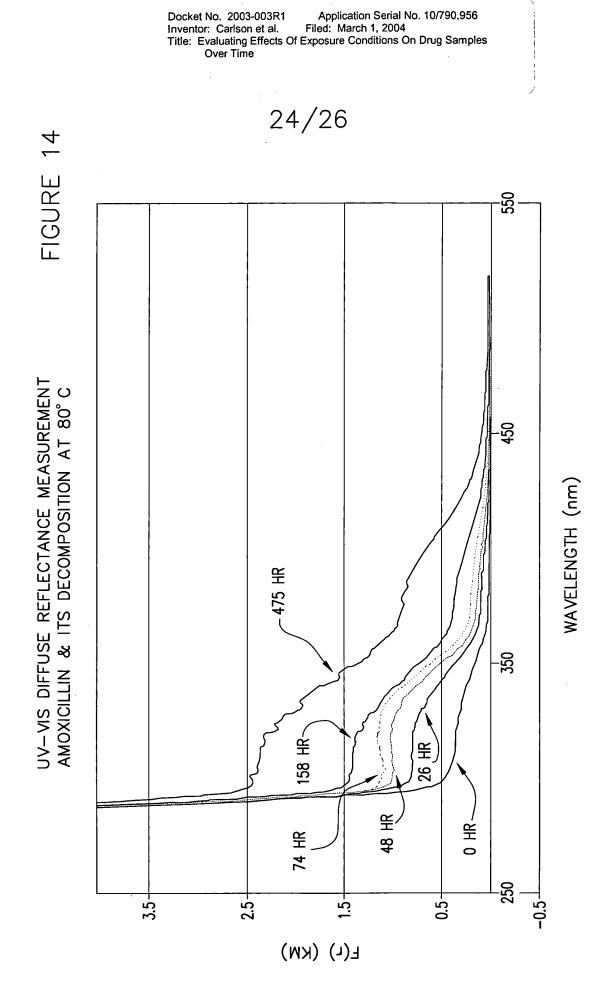
2.50

10.00

7.50

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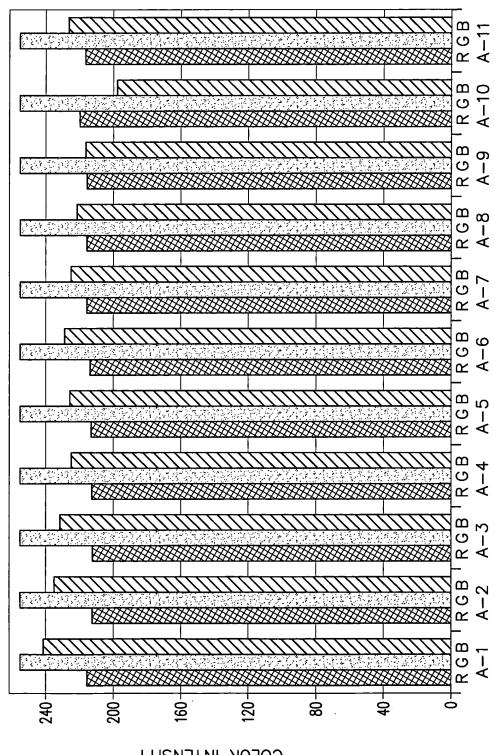


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COLORS OF AMOXICILLIN BATCH-1 SAMPLES



SAMPLE NUMBER

COLOR INTENSITY

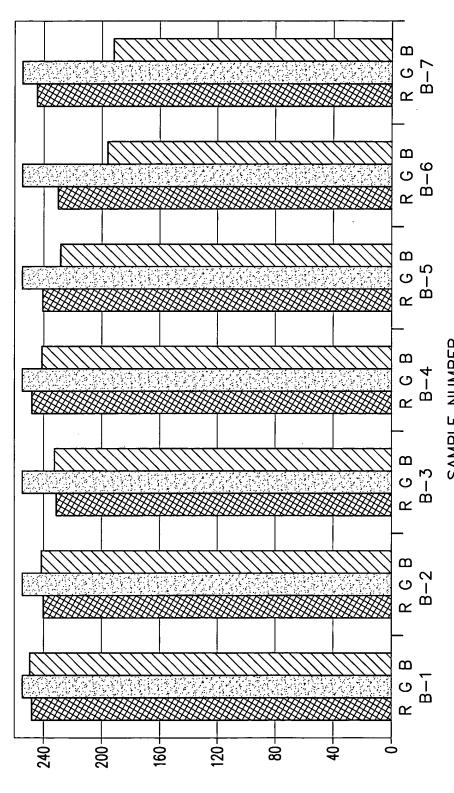
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COLOR OF AMOXICILLIN BATCH-2 SAMPLES

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% OF COLOR INTENSITY